REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claims 6 and 10 have been amended to recite that the active agent is dispersed in a matrix comprising one or more waxes, and to recite particular enteric film coatings. Support for these amendments is found on page 3, lines 12-14 and 24-25; page 6, lines 14-21; and Examples 1-4 (methacrylic acid copolymer LD (Eudragit L30D-55)) of Applicant's specification.

Claims 6, 7, 9, 10 and 11 have been amended to make editorial changes, in order to better comply with U.S. practice.

Claims 9, 11 and 12 have been amended to depend on claim 6.

Claims 1-5, 8 and 13-20 have been cancelled, without prejudice or disclaimer.

New claims 21-23 have been added to the application. Support for the new claims is found on page 6, lines 13 and 22-29; page 8, line 4; and Examples 1 and 4 (hydrogenated oil), Example 2 (carnauba wax) and Example 3 (stearic acid) of Applicant's specification.

No new matter has been added to the application by these amendments.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 2, 6, 7, 8 and 13-20 as being indefinite under 35 U.S.C. § 112, second paragraph has been rendered moot in view of the above-discussed claim amendments.

The amended claims do not contain any of the terms "base", "type" and "kind". The word "base" has been deleted from claims 6 and 7. Additionally, claims 2, 8 and 13-20 have been cancelled, without prejudice. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Rejection Under 35 U.S.C. § 102(b)

The rejection of claims 1-4, 8, 9 and 12-14 under 35 U.S.C. § 102(b) as being anticipated by Abe et al. (U.S. Patent Pub. 2002/0091152) has been rendered moot by the claim amendments.

This rejection does not include claim 6. As discussed above, claim 1 has been cancelled, without prejudice, and claims 6 and 10 are now the only independent claims. Accordingly, claim 6 (which was not included in the above-rejection), as well as dependent claims 9 and 12 are not anticipated by the cited reference. [Claims 1-4, 8, 13 and 14 have been cancelled, without prejudice.]

Rejections Under 35 U.S.C. § 103(a)

The rejection of claims 4, 5, 11 and 15-20 under 35 U.S.C. § 103(a) as being unpatentable over Abe et al. and further in view of Remington (1995); as well as the rejection of claims 6, 7 and 10 under 35 U.S.C. § 103(a) as being unpatentable over Abe et al. and Remington, and further in view of Itoh et al. (U.S. 5,194,464) are respectfully traversed.

The Position of the Examiner

The Examiner takes the position that Abe et al. teach a medicament comprised of alkylenedioxybenzene derivatives of formula I and pharmaceutically acceptable salts thereof.

The Examiner admits that Abe et al. do not teach a matrix comprised of wax, or that the active agent and the wax matrix are coated with a coating agent containing a synthetic polymer.

The Examiner states that Remington teaches that there are four categories of non-immediate-release delivery systems including sustained, controlled release. The Examiner states that an oral dosage form for sustained release is a matrix device, where a drug is dispersed as a solid in an inert matrix. The Examiner asserts that it would have been obvious to modify the composition of Abe et al. to include a matrix device and an enteric coating motivated by the desire to modify release of the active ingredient and thereby decrease or eliminate local and systemic effects and improve the efficiency of the treatment as taught by Remington.

The Examiner also admits that Abe et al. and Remington fail to teach a granule comprised of wax and an excipient, coated with an enteric film.

The Examiner states that Itoh et al. teach an enteric film comprised of a mixture of hydroxypropylcellulose phthalate, polyethylene glycol and shellac. The Examiner states that it would have been obvious to modify the form of the composition suggested by combining Abe et al. and Remington to the enteric coated granules of Itoh et al., motivated by the desire to produce a pharmaceutical composition that has constant absorption rate and is not influenced by meals as taught by Itoh et al.

Applicant's Arguments

Applicant respectfully disagrees with the Examiner's position for the following reasons.

Applicant has amended the claims to recite a composition and a process for preparing the composition, wherein the composition has two basic aspects: i) a granule comprising an alkylenedioxybenzene derivative represented by general formula (I) dispersed in a matrix comprising one or more waxes, and ii) the granule is coated with a specific enteric film. Additionally, (a) the matrix material has been amended to comprise one or more waxes, (b) the polymeric matrix material has been deleted, (c) the enteric film coating is amended to a specific

coating material, and (d) the wax as coating material has been deleted.

Independent claim 6 is not drawn to a composition comprising ordinary pharmaceutical additives, including fillers, such as cellulose, mannitol and lactose. Similarly, independent claim 10 is not drawn to a process of preparing a composition comprising ordinary pharmaceutical additives. On the contrary, the amended claims require a specific composition (and process of making) which comprises a granule comprising the recited compound dispersed in a matrix comprising one or more waxes, and coated with a specific coating.

As stated above, the Examiner admits that Abe et al. fail to teach a matrix comprised of wax, and Remington fails to teach granules comprised of a wax matrix and excipient, coated with an enteric coating. Thus, the Examiner relies on Itoh et al. However, Itoh et al., which is relied on as teaching enteric coatings, fails to teach Applicant's specific enteric coating. Thus, the cited combination of references fails to teach or suggest each and every limitation of Applicant's claims.

Further MKC-242 (a compound encompassed by Applicant's claims and specifically recited in claim 12) or its derivative has pH-dependent solubility, and dissolves much more in acidic conditions, as in the stomach, than in neutral or basic conditions, as in the intestines. If MKC-242 or its derivative is released in the stomach, it is very difficult to control its release, because the pH of the stomach varies from 1.8 to 4.5, depending on each human or their condition. Therefore, MKC-242 or its derivative is ordinarily not suitable for an oral regulated/prolonged release dosage form. (Please see page 2, lines 7-10 of Applicant's specification.)

However, Applicant has discovered a solution to this problem, which is the composition and process of Applicant's claims. In particular, Applicant discovered that the recited composition controls the desired release of MKC-242 or its derivative, while not resulting in adverse events, such as nausea, dizziness, orthostatic syncope. (Please see Experimental Example 2, on pages 11 and 12 of Applicant's specification.)

The cited combination of references fails to teach or suggest Applicant's claimed composition or process. Additionally, the cited combination of references fails to teach or suggest the unexpected advantages resulting from Applicant's invention.

Accordingly, the subject matter of Applicant's claims is clearly patentable over Abe et al., in view of Remington and/or further in view of Itoh. Accordingly, Applicant respectfully requests that these rejections be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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